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## UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: Jeannette Whitcomb

Confirmation No.: 4994

Serial No.: 10/758,683

Art Unit: 1648

Filed: January 14, 2004

Examiner: Parkin, Jeffrey S.

For: MEANS AND METHODS FOR  
MONITORING NON-NUCLEOSIDE  
REVERSE TRANSCRIPTASE  
INHIBITOR ANTIRETROVIRAL  
THERAPY AND GUIDING  
THERAPEUTIC DECISIONS IN THE  
TREATMENT OF HIV/AIDS

Attorney Docket No: 11068-078-999

**SECOND INFORMATION DISCLOSURE STATEMENT**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

In accordance with the duty of disclosure provisions of 37 C.F.R. §1.56, there is hereby provided certain information which the Examiner may consider material to the examination of the subject U.S. patent application. It is requested that the Examiner make this information of record if it is deemed material to the examination of the application.

1. Enclosures accompanying this Information Disclosure Statement are:

1a. ☒ A list of all patents, publications, applications, or other information submitted for consideration by the office.

1b. A legible copy of :

☒ Each U.S. patent application publication and U.S. and foreign patent;☒ Each publication or that portion which caused it to be listed on the PTO-1449;☐ For each cited pending U.S. application, the application specification including the claims, and any drawing of the application, or portion of the application which caused it to be listed on the PTO-1449 including any claims directed to that portion;☐ all other information or portion which caused it to be listed on the PTO-1449.1c. ☒ An English language copy of search report(s) from a counterpart foreign application or PCT International Search Report.1d. ☐ Explanations of relevancy (ATTACHMENT 1(d), hereto) or English language abstracts of the non-English language publications.2. ☒ This Information Disclosure Statement is filed under 37 C.F.R. §1.97(b):☐ Within three months of the filing date of a national application other than a continued prosecution application under §1.53(d);

- ☐ Within three months of the date of entry of the national stage as set forth in §1.491 in an international application;
- ☒ Before the mailing of the first Office action on the merits;
- ☐ Before the mailing of a first Office action after the filing of a request for continued examination under §1.114.

3. ☐ This Information Disclosure Statement is filed under 37 C.F.R. §1.97(c) after the period specified in 37 C.F.R. §1.97(b), but before the mailing date of any of a final action under 37 C.F.R. §1.113, a notice of allowance under 37 C.F.R. §1.311 or an action that otherwise closes prosecution in the application.

*(Check either Item 3a or 3b)*

- 3a. ☐ The Certification Statement in Item 5 below is applicable. Accordingly, no fee is required.
- 3b. ☐ The \$180.00 fee set forth in 37 C.F.R. §1.17(p) in accordance with 37 C.F.R. §1.97(c) is:
- ☐ enclosed
  - ☐ to be charged to Jones Day Deposit Account No. 50-3013.

*(Item 3b to be checked if any reference known for more than 3 months)*

4. ☐ This Information Disclosure Statement is filed under 37 C.F.R. §1.97(d) after the period specified in 37 C.F.R. §1.97(c), but on or before the date of payment of the issue fee.

The \$180.00 fee set forth in 37 C.F.R. §1.17(p) is:

- ☐ enclosed.
- ☐ to be charged to Jones Day Deposit Account No. 50-3013.

The Certification Statement in Item 5 below is applicable.

5. ☐ Certification Statement (applicable if Item 3a or Item 4 is checked)

*(Check either Item 5a or 5b)*

- 5a. ☐ In accordance with 37 C.F.R. §1.97(e)(1), it is certified that each item of information contained in this Information Disclosure Statement was first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement.
- 5b. ☐ Each item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart application, and the communication was not **received** by any individual designated in 37 C.F.R. §1.56(c) more than thirty days prior to the filing of this information disclosure statement.
- 5c. ☐ Pursuant to 37 C.F.R. §1.704(d), each item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart application, and the communication was not **received** by any individual designated in 37 C.F.R. §1.56(c) more than thirty days prior to the filing of this information disclosure statement.

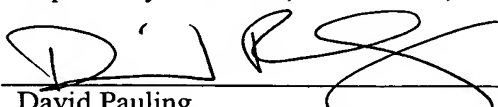
6. ☐ This application is a continuation application under 37 C.F.R. §1.60 or §1.53(b) or (d).

(Check appropriate Items 6a, 6b and/or 6c)

- 6a. ☐ A Petition to Withdraw from issue under 37 C.F.R. §1.313(b)(5) is concurrently filed herewith.
- 6b. ☐ Copies of publications listed on Form PTO-1449 from prior application Serial No., filed on, of which this application claims priority under 35 U.S.C. §120, are not being submitted pursuant to 37 C.F.R. §1.98(d).
- 6c. ☐ Copies of the publications listed on Form PTO-1449 were not previously cited in prior application Serial No. , filed on , and are provided herewith.
7. ☐ This is a Supplemental Information Disclosure Statement. (Check Item 7a)
- 7a. ☐ This Supplemental Information Disclosure Statement under 37 C.F.R. §1.97(f) supplements the Information Disclosure Statement filed on . A bona fide attempt was made to comply with 37 C.F.R. §1.98, but inadvertent omissions were made. These omissions have been corrected herein. Accordingly, additional time is requested so that this Supplemental Information Disclosure Statement can be considered as if properly filed on .
8. ☐ In accordance with 37 C.F.R. §1.98, a concise explanation of what is presently understood to be the relevance of each non-English language publication is:
- ( Check Item 8a, 8b, or 8c)
- 8a. ☐ satisfied because all non-English language publications were cited on the enclosed English language copy of the PCT International Search Report or the search report from a counterpart foreign application indicating the degree of relevance found by the foreign office.
- 8b. ☐ set forth in the application.
- 8c. ☐ enclosed as an attachment hereto.
9. ☒ The Commissioner is authorized to charge any additional fee required or credit any overpayment for this Information Disclosure Statement and/or Petition to to be charged to Jones Day Deposit Account No. 50-3013.
10. ☒ No admission is made that the information cited in this Statement is, or is considered to be, material to patentability nor a representation that a search has been made (other than a search report of a foreign counterpart application or PCT International Search Report if submitted herewith). 37 C.F.R. §§1.97(g) and (h).

Respectfully submitted,

Date: December 3, 2004

  
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56,056  
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**LIST OF REFERENCES CITED BY APPLICANT**  
(Use several sheets if necessary)

ATTY DOCKET NO.

APPLICATION NO.

011068-078-999

10/758,683

APPLICANT

Whitcomb, Jeanette

FILING DATE

GROUP

January 14, 2004

1648

**U.S. PATENT DOCUMENTS**

*EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
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**FOREIGN PATENT DOCUMENTS**

	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION
						YES NO
B01	WO97/27332	7/97	PCT			
B02	WO97/27319	7/97	PCT			
B03	European Search Report for EP 0194452	10/04	EPO			
B04	European Search Report for EP 99933581	9/04	EPO			
B05	European Search Report for EP 99925874	9/04	EPO			

**OTHER REFERENCES** (Including Author, Title, Date, Pertinent Pages, Etc.)

B06	Buckheit, <i>et al.</i> (1995) "Resistance to 1-[(2-hydroxyethoxy)methyl]-6-(phenylthio)thymine Derivatives is Generated by Mutations at Multiple Sites in the HIV-1 Reverse Transcriptase", <i>Virology</i> 210(1):186-193.
B07	Esnouf, <i>et al.</i> (1997) "Unique Features in the Structure of the Complex Between HIV-1 Reverse Transcriptase and the bis(heteroaryl)piperazine (BHAP) U-90152 Explain Resistance Mutations for this Nonnucleoside Inhibitor", <i>PNAS</i> 94(8) 3984-3989.
B08	Fan <i>al.</i> 1995 "Mechanism of Resistance to U-90152S and Sensitization to L-697, 661 by a Proline to Leucine Change at Residue 236 of Human Immunodeficiency Virus Type-1 (HIV-1) Reverse Transcriptase", <i>FEBS Letters</i> 359(2-3): 233-238.
B09	Kanki, <i>et al.</i> (1997) "Virology of HIV-1 and HIV-2: Implications for Africa", <i>AIDS</i> 11(Supp. B): S33-S42.
B10	Mellors, <i>et al.</i> (1995) "Mutations in HIV-1 Reverse Transcriptase and Protease Associated with Drug Resistance", <i>International Antiviral News Volume 3</i> : 8-13.
B11	Romero, <i>et al.</i> (1996) "Targeting Delavirdine/Ateviridine Resistant HIV-1: Identification of Piperidine-Containing bis(heteroaryl) piperazines as Broad Spectrum HIV-1 Reverse Transcriptase Inhibitors", <i>Journal of Medicinal Chemistry</i> 33(19) 3769-3789.
B12	Salomon, <i>et al.</i> (2000) "Prevalence of HIV-1 Resistant to Antiretroviral Drugs in 81 Individuals Newly Infected By Sexual Contact or Injecting Drug Use", <i>AIDS (London, England)</i> 14(2): F17-F23.

**EXAMINER****DATE CONSIDERED**

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.